UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOT FOR PUBLICATION

IN RE: FETZIMA

Civil Action No.

OPINION ON DISCOVERY DISPUTE

2:17-CV-10230-ES-SCM

D.E. 145-146

Steven C. Mannion, United States Magistrate Judge.

Before this Court is the parties' joint agenda letter dated May 14, 2019, wherein Defendants remind the Court that fact discovery closes on June 12, 2019 and argue "that the case must proceed with the current date for the close of fact discovery."[1] Also before the Court is the parties' informal joint dispute letter and attachments totaling approximately 100 pages filed around 7:00 p.m. on May 21, 2019[2]—the evening prior to the Court's telephone conference with the parties. In sum, Defendant Torrent seeks an order compelling Plaintiffs to produce Active Pharmaceutical Ingredient ("API") samples for Fetzima®.[3] Torrent also seeks manufacturing records documenting the process used to make the Fetzima product.[4] The Court has reviewed the parties' submissions

[1] (Electronic Case Filing Docket Entry ("D.E.") 143, Joint Agenda Letter, at 1–2). Unless indicated otherwise, the Court will refer to documents by their docket entry number and the page number assigned by the Electronic Case Filing System.

[2] (D.E. 145 & 146, Joint Dispute Letter).

[3] (D.E. 145, Joint Dispute Letter, at 1–3).

[4] (*Id.*).

and heard oral argument on May 22, 2019. For the reasons stated below, Defendant Torrent's informal motion to compel is **DENIED**.

I. BACKGROUND AND PROCEDURAL HISTORY[5]

In October 2017, Plaintiffs commenced this action.[6] In February 2018, this Court ordered consolidation for all purposes of seven actions concerning the patents for Fetzima®.[7] The defendants include Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals Private Limited, Aurobindo Pharma USA, Inc. and Aurobindo Pharma Limited, MSN Laboratories Private Limited and MSN Pharmaceuticals Inc., Prinston Pharmaceutical Inc. and Solco Healthcare U.S., LLC, Torrent Pharmaceuticals Limited and Torrent Pharma Inc., West-Ward Pharmaceuticals International Limited and Hikma Pharmaceuticals USA Inc., and Zydus Pharmaceuticals (USA) Inc. (collectively "Defendants").[8]

The parties filed their joint discovery plan on February 27, 2018.[9] The parties explain that Plaintiffs instituted seven actions under 21 U.S.C. § 355, the Hatch-Waxman Act, for infringement of three patents against Defendants.[10] These actions are based on Defendants' submissions of separate Abbreviated New Drug Applications ("ANDAs") to the U.S. Food and Drug Administration ("FDA") seeking approval to sell generic versions of levomilnacipran

[5] The allegations set forth within the pleadings and motion record are relied upon for purposes of this motion only. The Court has made no findings as to the veracity of the parties' allegations.

[6] (D.E. 1, Compl.).

[7] (D.E. 22, Order)

[8] (D.E. 101, Defs.' Br., at 5, n.1).

[9] (D.E. 27, Joint Discovery Plan).

[10] (*Id*., at 2).

hydrochloride, brand name Fetzima®, before the expiration of the three patents.[11] Fetzima® is sold in the United States for the treatment of major depressive disorder.[12] The three patents are listed in the FDA's publication *Approved Drug Products with Therapeutic Equivalents* (known as the "Orange Book") as associated with Fetzima®.[13]

According to the joint discovery plan, Defendants Prinston, Amneal, Zydus, MSN, West-Ward, and Aurobindo each stated that they would make available to the Plaintiffs relevant and non-privileged ANDA product research and development documents at a reasonable mutually agreeable time and location.[14] Each also stated that their samples of the capsules of their respective ANDA products are located outside of the United States and would be available to Plaintiffs.[15] Torrent stated that it would make available to the Plaintiffs relevant and non-privileged ANDA product research and development documents at a reasonable mutually agreeable time and location; however, did not agree to produce samples.[16]

On March 7, 2018, the Court held the initial scheduling conference and entered its Pre-trial Scheduling Order.[17] In December 2018, Plaintiffs sought and obtained an order compelling

[11] (*Id*.).

[12] (*Id*.).

[13] (*Id*.).

[14] (*Id*., at 13–15).

[15] (D.E. 27, Joint Discovery Plan, at 13–15).

[16] (*Id*., at 14–15).

[17] (D.E. 34, Sched. Order).

Prinston to produce API samples.[18] Fact discovery closes June 12, 2019.[19] The parties have a scheduled Markman hearing on August 15, 2019 to be heard by the Honorable Esther Salas, U.S.D.J.[20]

The parties filed their joint dispute letter on May 21, 2019.[21]

II. MAGISTRATE JUDGE AUTHORITY

Magistrate judges are authorized to decide any non-dispositive motion designated by the Court.[22] This District specifies that magistrate judges may determine all non-dispositive pre-trial motions which includes discovery motions.[23] Decisions by magistrate judges must ordinarily be upheld unless "clearly erroneous or contrary to law,"[24] but where the decision concerns a discovery dispute, the ruling "is entitled to great deference and is reversible only for abuse of discretion."[25]

III. DISCOVERY STANDARD

Case management and discovery are a collaborative process that begins with the Court's order for counsel to hold their initial meeting to prepare a joint discovery plan.[26] A party or attorney

[18] (D.E. 100, Order).

[19] (D.E. 34, Sched. Order, at ¶ 17).

[20] (D.E. 134, Text Order).

[21] (D.E. 145 & 146, Joint Dispute Letter).

[22] 28 U.S.C. § 636(b)(1)(A).

[23] L. CIV. R. 72.1(a)(1); 37.1.

[24] § 636(b)(1)(A).

[25] *Kresefky v. Panasonic Commc'ns & Sys. Co.*, 169 F.R.D. 54, 64 (D.N.J. 1996); *Cooper Hosp./Univ. Med. Ctr. v. Sullivan*, 183 F.R.D. 119, 127 (D.N.J. 1998).

[26] Fed. R. Civ. P. 26(f).

may be sanctioned for failing "to participate in good faith in developing and submitting a proposed discovery plan."[27] The Local Patent Rules further require that a discovery plan must address the "availability and timing of production of ANDA product samples."[28]

Federal Rule of Civil Procedure 1 mandates that each of these rules "be construed, administered, and employed by the court and the parties to secure the just, speedy, and inexpensive determination of every action and proceeding."[29] Judges and attorneys share the responsibility "to ensure that civil litigation is resolved not only fairly, but also without undue cost or delay."[30]

"Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit."[31] "Although the scope of discovery under the Federal Rules is broad, this right is not unlimited and may be circumscribed."[32]

Federal courts employ a burden-shifting analysis to resolve discovery disputes. A party seeking to compel discovery bears the initial "burden of showing that the information sought is

[27] Fed. R. Civ. P. 37(f).

[28] L. Pat. R. 2-1(a)(6).

[29] Fed. R. Civ. P. 1.

[30] *Atlas Res., Inc. v. Liberty Mut. Ins. Co.*, 297 F.R.D. 482, 485 (D.N.M. 2011) (citation omitted).

[31] Fed. R. Civ. P. 26(b)(1).

[32] *Bayer AG v. Betachem, Inc.*, 173 F.3d 188, 191 (3d Cir. 1999).

relevant to the subject matter of the action."[33] Evidence is relevant if "it has any tendency to make a fact more or less probable than it would be without the evidence" and "the fact is of consequence in determining the action."[34]

That is because the sole purpose of discovery is to add flesh for trial on the parties' respective claims and defenses in the given action. Discovery is not a fishing expedition for potential claims or defenses.[35] Still, district courts must remain mindful that relevance is a broader inquiry at the discovery stage than at the trial stage.[36]

If the party seeking discovery meets the burden, "the objecting party must specifically show how each discovery request is objectionable."[37] "The responding party shall use common sense and reason, and hyper-technical, quibbling, or evasive objections will be viewed unfavorably."[38] Objections must state with specificity the objection and how it relates to the particular request being opposed, and not merely that it is "overly broad and burdensome" or "oppressive" or "vexatious" or "not reasonably calculated to lead to the discovery of admissible evidence."[39] "The burden [is upon] the party resisting discovery to clarify and explain its

[33] *Caver v. City of Trenton*, 192 F.R.D. 154, 159 (D.N.J. 2000).

[34] Fed. R. Evid. 401.

[35] *Smith v. Lyons, Doughty & Velduius, P.C.*, No. 07-5139, 2008 WL 2885887, at *5 (D.N.J. July 23, 2008).

[36] *Nestle Foods Corp. v. Aetna Cas. & Sur. Co.*, 135 F.R.D. 101, 104 (D.N.J. 1990).

[37] *Kannaday v. Ball*, 292 F.R.D. 640, 644 (D. Kan. 2013).

[38] *Lamon v. Adams*, No. 09-205, 2014 WL 309424 (E.D. Cal. 2014).

[39] *Harding v. Dana Transp., Inc.*, 914 F. Supp. 1084, 1102 (D.N.J. 1996).

objections and to provide support therefor."[40] Failure to meet this standard may result in waiver of an objection.[41]

IV. DISCUSSION AND ANALYSIS

Torrent seeks samples of the API in Fetzima® and the production of manufacturing records documenting the process used to make the Fetzima® product. The Court will first consider the parties' arguments.

As to the samples, Torrent asserts that they are "highly relevant to several issues in the case."[42] Torrent argues that "whether Fetzima® actually contains a crystalline form that is claimed by the '937 patent is a predicate factual allegation that supports this entire case," and this is now an issue because discovery revealed that the active ingredient in Fetzima® may not contain any crystalline form claimed in the '937 patent.[43] Plaintiffs disagree and instead contend that the ANDA application is the fundamental element because this case concerns whether Defendants' ANDA products infringe on Plaintiffs' patents and whether Defendants can establish that the patents are invalid.[44] Plaintiffs note that Torrent does not argue that the sought discovery is relevant to Torrent's allegations of non-infringement or invalidity.[45]

Torrent further argues that the samples are relevant to establishing a nexus between the asserted claims in the '937 patent as Plaintiffs have contended that unexpected clinical benefits

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[40] *Id.* (alteration in original) (citations omitted).

[41] *Id.* (citations omitted).

[42] (D.E. 145, Joint Dispute Letter, at 2).

[43] (*Id.*).

[44] (*Id.*, at 3).

[45] (*Id.*).

arise from the use of Fetzima®.[46] Torrent appears to also make the same arguments for the '598 and '879 patents.[47] Plaintiffs argue that Torrent misrepresents Plaintiffs' contentions and asserted claims, and that Torrent lacks supporting citations for its claims.[48] Plaintiffs specifically note that Torrent's citation for its contention regarding the '937 patent relates only to the '598 and '879 patents, and the claims of those patents do not include a requirement for a particular crystalline form of levomilnacipran.[49] Thus, they argue that any non-clinical testing by Defendants on levomilnacipran API samples have no bearing on unexpected clinical results obtained by levomilnacipran.[50] As to the '937 patent, Plaintiffs assert that they have not alleged unexpected clinical benefits as an objective indicia of non-obviousness, deeming the proof of a nexus to be irrelevant.[51]

As to both the samples and manufacturing records, Torrent alleges that this discovery is relevant to Torrent's belief that Plaintiff falsely alleged that Defendants copied Fetzima® in connection with FDA approval of ANDAs.[52] Plaintiffs explain that they have made efforts to resolve this issue by providing Defendants with a proposed stipulation agreeing that Plaintiffs would not raise Defendants copying of Fetzima® as an objective indicia of non-obviousness with

[46] (*Id*., at 2–3).

[47] (*Id*., at 3).

[48] (D.E. 145, Joint Dispute Letter, at 5–6).

[49] (*Id*., at 5).

[50] (*Id*., at 5–6).

[51] (*Id*., at 6).

[52] (*Id*., at 2).

respect to the asserted claims of the '937 patent.[53] However, Defendants rejected the proposal.[54] Plaintiffs produced the drug master file ("DMF") for Fetzima®, which they argue provides the details related to the process used to make Fetzima® and production of every manufacturing batch record would be voluminous, unduly burdensome, and duplicative.[55] Plaintiffs assert that the process for how Fetzima® is made is irrelevant and that Torrent fails to establish otherwise.[56]

After reviewing the parties' arguments, the Court next determines whether Torrent meets its burden of demonstrating relevancy. As an initial matter, Torrent did not identify the production of API in Fetzima® or manufacturing records within the joint discovery plan. In fact, Torrent did not request this production until 11 months into discovery, and now argues that such discovery is "highly relevant." Interestingly, Torrent did not agree nor has been ordered to produce samples.

API samples are often ordered in patent cases, as they have been in this case;[57] yet the orders are commonly directed at defendants, not plaintiffs. Torrent has not asserted a counterclaim against Plaintiffs, nor has any defendant. "Discovery is meant to bear on the claims and defenses actually present in a matter."[58] "The discovery rules are designed to assist a party to prove a claim it reasonably believes to be viable without discovery, not to find out if it has any basis for a

[53] (*Id*., at 4, Ex. F).

[54] (D.E. 145, Joint Dispute Letter, at 4–5, Ex. G).

[55] (*Id*., at 6).

[56] (*Id*.).

[57] (*See* D.E. 100, Order).

[58] *Martinez v. Fuentes*, No. 15-2932, 2017 WL 2345703, at 5 (D.N.J. May 20, 2017).

claim."[59] Torrent fails to provide any case law in which a court ordered a plaintiff, as a patent owner alleging patent infringement, to produce API samples, and instead relies on cases where defendants were ordered to make such production. At oral argument, Torrent acknowledged that the samples and manufacturing records may lead to a counterclaim, but this is an improper use of the discovery process, especially many months into discovery.

Torrent fails to identify the discovery that it relies on as a basis for testing API samples, mainly what discovery indicates that the active ingredient in Fetzima® may not contain any crystalline form claimed in the '937 patent. This case concerns whether Defendants' ANDA products infringe on Plaintiffs' patents and whether those patents are invalid. Torrent has not demonstrated any differently. Much of Torrent's argument contains conclusory statements without any support either from the record or case law. It has not proffered a good faith basis for the justification of the discovery requested or for the Court to ignore the Local Patent Rules requiring counsel to have addressed the production of samples in the joint discovery plan.

Torrent's delay and deficient reasoning for the requested discovery leads the Court to find that Torrent is engaging in nothing more than a fishing expedition for potential claims or defenses. Torrent does not explain how the sought discovery is relevant to non-infringement or invalidity of Plaintiffs' patents and it improperly cites unrelated patents in support of its argument for a nexus between asserted claims and unexpected clinical benefits. As to both the API samples and manufacturing records, Torrent has not met its burden of demonstrating that Plaintiffs' stipulation related to copying of Fetzima® is insufficient. Torrent neglects the significance of the already produced DMF and does not specify how the production of manufacturing records would not be

[59] *Claude P. Bamberger Intern., Inc. v. Rohm and Haas Co.*, No. 96-1041, 1998 WL 684263, *2 (D.N.J. April 1, 1998) (quoting *Micro Motion, Inc. v. Kane Steel Co., Inc.*, 894 F.2d 1318, 1326 (Fed. Cir. 1990)).

duplicative or how the DMF is an insufficient production. At this time, the Court is hard pressed to find that testing the API in Fetzima® or manufacturing records will offer any information relevant to Plaintiffs' infringement claims.

V. CONCLUSION

For the foregoing reasons, this Court **DENIES** Defendant Torrent's informal motion to compel.

An appropriate Order follows:

ORDER

IT IS on this Thursday, June 06, 2019,

ORDERED, that Defendant Torrent's informal motion to compel is **DENIED**.

Honorable Steve Mannion, U.S.M.J.
United States District Court,
for the District of New Jersey
phone: 973-645-3827

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Original: Clerk of the Court
Hon. Esther Salas, U.S.D.J.
cc: All parties
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